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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,329	05/15/2001	Ricky Ah-Man Woo	8086	1099

27752 7590 08/27/2002

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EXAMINER	
KRISHNAN, GANAPATHY	
ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 08/27/2002 2

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/855,329	WOO ET AL.	
	Examiner	Art Unit	
	Ganapathy Krishnan	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) 1-16 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-16 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Defective Oath or Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 C.F.R. § 1.67(a) identifying this application by its Serial Number and filing date is required. See M.P.E.P. §§ 602.01 and 602.02.

The oath or declaration is defective because: the signature of one of the inventors (Dean L. Duval) and the date are missing.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10 and 12-15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 2-7 of U.S. Patent No. 5,942,217('217), over Claims 1 and 6-12 of U.S. Patent No. 5,997,759 ('759) and over Claims 1-4 of U.S. Patent No. 6,436,442 ('642) respectively.

Although the conflicting claims 1-10 are not identical to the '217 and '759 patents, they are not patentably distinct from the patents cited above because the claims of the instant application and the '217 and '759 patents are drawn to compositions containing cyclodextrin derivatives that overlap. The difference is that the instant claims recite a specific average degree of substitution for the cyclodextrins whereas the prior art recites a broad range for the degree of substitution. The average degree of substitution of the cyclodextrin derivatives of the instant application all fall within the range disclosed in the '217 and '759 patents (col.7, lines 46-52 of '217 patent, and col.8, line 56 to col.9 line 11 of '759 patent).

Claims 12-15 of the instant application are also seen to overlap with Claims 1-4 of the '442 patent. The instant claims recite cyclodextrin-compatible and cyclodextrin-incompatible surfactants whereas the '442 patent recites cyclodextrin-compatible and cyclodextrin-incompatible material. Both the '442 patent and instant application are drawn to analogous processes of manufacturing compositions and have overlapping limitations, such as providing the cyclodextrin, cyclodextrin-compatible material, cyclodextrin-incompatible material, combining the cyclodextrin-compatible and cyclodextrin-incompatible material to form a first mixture and then subsequently combining the cyclodextrin with the first mixture; forming a first aqueous mixture of the compatible and incompatible material and subsequently adding cyclodextrin to the first aqueous mixture; the said first mixture comprises said cyclodextrin-incompatible material solubilized in micelles or vesicles comprising said cyclodextrin-compatible material as molecular aggregates.

In spite of the differences stated above, it would have been obvious to one of ordinary skill in the art that the composition and the process of the instant application and the '217, '759 and '442 patents are substantially overlapping. The process and composition of the instant invention must contain new distinguishable measures over the prior art.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 5, 6, 11, 12, and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "low-degree" in claims 1, 2, 5, 6, 11, 12, is a relative term that renders the claim indefinite. The term "low-degree" is not defined by the claim, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Either the degree of substitution should be recited in the claims or the terms "low-degree of substitution" should be removed. Claim 16 is rendered indefinite since it depends on Claim1, which recites "low-degree".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trinh et al (USPN 5,997,759) in combination with Trinh et al (USPN 5,578,563), Woo et al (USPN 5,942,217).

Claims 1-10 are drawn to a composition comprising low-degree of substitution cyclodextrin derivative; wherein the derivatives are hydroxyalkyl and alkyl; wherein the composition comprises non derivatized cyclodextrin selected from the group consisting of alpha-cyclodextrin, beta-cyclodextrin, gamma-cyclodextrin and mixtures thereof.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Trinh et al (USPN 5,997,759), Trinh et al (USPN 5,578,563) and Woo et al (USPN 5,942,217) all teach the use of cyclodextrins and its derivatives in compositions. The degree of substitution of the alkylated derivative, methylated in particular, is typically in the range of from about 3 to about 16 (USPN 5,942,217, col.7, line 49-52; USPN 5,578,563, col. 10, lines 64-66; USPN 5,997,759, col. 8, lines 64-66). Hydroxyalkyl cyclodextrin derivatives have a degree of substitution preferably from about 1.5 to about 7 (USPN 5,942,217, col. 7, line 45-48; USPN 5,578,563, col.10, lines 60-62; USPN 5,997,759, col. 8, lines 60-63).

The difference between the prior art cited above and the instant claims is that the instant claims recite a specific average degree of substitution for the hydroxyalkyl and the alkyl cyclodextrins whereas the prior art discloses a broader range for the degree of substitution. The degree of substitution of the hydroxyalkyl and alkyl cyclodextrins used in the instant composition all fall within the range disclosed in the prior art.

In spite of this difference, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teachings of Trinh et al and Woo to make compositions containing various types of cyclodextrins with the average degree of substitution as instantly claimed.

A person of ordinary skill in the art would have been motivated to produce the instantly claimed composition because it can be used as the base composition to which various other ingredients can be added to prepare new compositions for unique sanitizing and cleansing purposes.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 703-305-4837. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 703-308-4532. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

GK
August 23, 2002

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